K003315

NOV - 8 2000

MALLINCKRODT

510(k) Summary

Mallinckrodt Inc.

Shiley Tracheosoft XLT Extended Length Tracheostomy Tube and Disposable Inner Cannula

Submitter Information

Submitter: Mallinckrodt Inc.
3 Missouri Research Park Drive
St. Charles, MO 63304.

Contact: James C. Keeven
Regulatory Affairs Associate
Tel: (636) 498 3431
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Preparation Date: October 17, 2000

Device Name

Proprietary Name: Shiley Tracheosoft XLT Extended Length Tracheostomy Tube and Disposable Inner Cannula
Common Name: Trachestomy Tube and tube cuff
Classification Name: Tracheostomy Tube and tube cuff (73 JOH) as per 21 CFR 868.5800

Predicate Device Equivalence

Mallinckrodt Inc. is claiming substantial equivalence to Shiley Extended length, Disposable Cannula, Tracheostomy Tubes, (K971267).

Device Description

The Mallinckrodt Inc. Shiley Tracheosoft XLT Extended Length Tracheostomy Tube and Disposable Inner Cannula includes an extended length outer cannula, extended length disposal inner cannula, tracheostomy tube holder, neck strap and obturator.
The device is used to provide an artificial airway, in order to assist in the treatment of a variety of respiratory diseases and airway management in adults. The device is inserted into a tracheotomy incision in a patient's neck and trachea. The device is secured in place through the tracheostomy tube's swivel neck plate/flange with the use of a tracheostomy tube holder or neck strap. Once secure, the device provides a secure artificial airway for spontaneous breathing or direct hook-up to ventilation or anesthesia equipment.

Intended Use

The intended use of the modified Mallinckrodt Inc. Shiley Tracheosoft XLT Extended Length Tracheostomy Tube and Disposable Inner Cannula is intended to be placed into a surgical opening of the trachea to facilitate ventilation to the lungs. The cuff is intended to establish a seal between the tracheal wall and the tracheostomy tube. This device is intended to be a component of a life sustaining device to be used for airway management in adults. The device is contraindicated regarding procedures involving the use of lasers.

Comparison of Technological Characteristics

The intended use of the modified device remains unchanged as does its risk classification. The modified device will continue to be indicated for the same patient population and will continue to be a prescription only device. Both devices are intended to be a component of a life sustaining device which is to be used for airway management in adults.
To achieve consistency between this product range and other similar products manufactured by Mallinckrodt, a warning statement currently listed in the instruction for use on the unmodified device has been elevated to a contraindication statement.

Both the modified and unmodified device include an extended length outer cannula, extended length disposal inner cannula, neck strap and obturator. A tracheostomy tube holder is being added to the modified device. Both devices continue to have cuffed and uncuffed verisons.
To optimize the locking feature between the inner and outer cannulas, the locking mechanism has been redesigned. As part of this redesign, the component material has been changed.
Both devices have a swivel neck flange however, the modified devices' has been reduced in size to improve patient comfort.
A step feature on the distal end of the outer cannula had been added to the modified device. This feature will aid in reducing any potential leaking that may occur between the inner and outer cannulas.

Summary of Performance Testing

The Shiley Tracheosoft XLT Extended Length Tracheostomy Tube and Disposable Inner Cannula successfully passed tests per standards ISO 5366-1 : 2000 Anaesthetic and respiratory Equipment – Tracheostomy Tubes.

Conclusions

In summary, Mallinckrodt Inc. has demonstrated that the Shiley Tracheosoft XLT Extended Length Tracheostomy Tube and Disposable Inner Cannula is safe and effective. The combined testing and analysis of results provides assurance that the device meets its specifications and is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 8 2000

Mr. James C. Keeven
Mallinckrodt Inc.
3 Missouri Research Park Drive
St. Charles, MO 63304

Re: K003315
Shiley Tracheosoft XLT Extended Length Tracheostomy Tube and Disposable Inner Cannula
Regulatory Class: II (two)
Product Code: 73 JOH
Dated: October 17, 2000
Received: October 23, 2000

Dear Mr. Keeven:

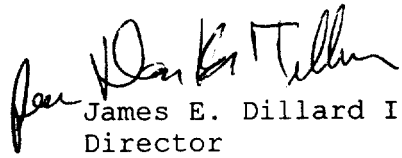
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

Device name: Shiley Tracheosoft XLT Extended Length Tracheostomy Tube and Disposable Inner Cannula

Indications for Use: The Mallinckrodt Inc. Shiley Tracheosoft XLT Extended Length Tracheostomy Tube and Disposable Inner Cannula are intended to provide tracheal access for airway management.

Prescription Use: Yes

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: X *or* Over-The-Counter Use: _____

Premarket Notification 510(k) Number: K003315

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K003315